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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,962	08/11/2000	Lawrence H. Thompson	500731.01	8001

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/637,962	THOMPSON, LAWRENCE H.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-68 and 76-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-68 and 76-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of Application, Amendments and/or Claims

The amendment filed 21 February 2001 (Paper No. 8) has been entered in full. Claims 1-65, 69-75 and 86-116 were cancelled. Applicant's election of Group V (claims 66-89) and species election of an anemia associated with renal condition (renal condition) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The amendment filed 17 June 2002 (Paper No. 11) has been entered in full. Applicant's species election of an erythropoietin produced in baby hamster kidney cells in Paper No. 11 is acknowledged. Claims 66-68 and 76-85 are under examination.

Drawings

The drawings are objected to because according to the description of drawings in the specification (page 12), Figure 24 should have four panels (Figure 24A-D), however only one panel is illustrated in Figure 24. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. No new matter may be introduced into the drawings.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites "....comprising administering a therapeutic amount of a recombinant erythropoietin...". The claim is indefinite because it does not state who (animal, human, subject, etc) the recombinant erythropoietin is being administered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-68 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Powell, US Patent No. 5,688,679. Powell teaches transfecting baby hamster kidney cells with the Apa I restriction fragment of the human erythropoietin gene (column 1, lines 56-66 and column 5, lines 11-67). The instant specification states that Epoetin Omega is produced in baby hamster kidney cells by expression from an Apa I restriction fragment of the human erythropoietin gene (page 4, 3rd paragraph-page 5, 1st

paragraph). The instant specification cites Powell as describing Epoetin Omega (page 4, 3rd paragraph). Thus, the Apa I restriction fragment of Powell is Epoetin Omega (recombinant erythropoietin). The biological potency of an erythropoietin preparation is estimated by the exhypoxic polycythemic mouse assay.

Powell teaches the administration of Epoetin Omega to exhypoxic polycythemic mice (subject). The terms "non-responsive" or "adversely effected" are vague words that can mean any effect caused by treatment with a therapeutic amount of Epoetin Alfa or Beta.

The supernatants secreted from the cell lines (baby hamster kidney cells) had potent *in vivo* biological activity when assayed in the exhypoxic polycythemic mouse (column 8, lines 14-32). Powell teaches that the hormone erythropoietin plays a major role in regulating erythropoiesis, the formation of red blood cells and deficiencies of erythropoietin result in anemia (column 1, lines 24-27). Powell teaches that patients with deficiencies of erythropoietin, such as those with chronic renal failure, often suffer severe anemia (column 1, lines 41-43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 77-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell in view of Strickland, US Patent No. 5,661,125. The teachings of Powell are

described above in the 102(b) rejection. Powell does not teach dosage amounts of recombinant erythropoietin.

Strickland teaches the production of recombinant erythropoietin in baby hamster kidney cells (column 5, lines 24-41). Strickland teaches recombinant erythropoietin dosages that overlap with the instant dosages claimed (column 5, lines 42-57). Furthermore, Strickland teaches that some patients experience local discomfort or stinging upon the subcutaneous administration of Epoetin Alfa (column 2, lines 12-22). The combination of a non-sting and multidose, ready-to-use solution formulation is highly desirable and meets several needs of the patient and caregiver (column 2, lines 33-35 and column 4, lines 7-16). Strickland teaches that the instant composition of erythropoietin preferably provides the dual benefits of being a multi-use or multi-dose solution and a reduction in the discomfort experienced by some patients upon injection of certain erythropoietin solution formulations (column 4, lines 23-88).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Powell regarding Epoetin Omega using the dosage teachings of Strickland. The motivation and expected success is provided by Powell who shows potent activity of Epoetin Omega transfected in baby hamster kidney cells by using the *in vivo* exhypoxic polycythemic mouse assay and the teachings of Strickland regarding dosages of erythropoietin. Strickland states that dose adjustments of erythropoietin are made by monitoring the hematocrit. Furthermore, adjustments and optimizations are deemed a matter of judicious selection and routine in the art. As was stated above, non-response or adverse effects of Epoetin Alfa or Beta

can be any side effect as Strickland teaches the stinging effect associated with Epoetin Alfa.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
September 5, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER